DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 9, 2015

Reliance Medical Systems, LLC
Mr. Bret M. Berry
Owner
P.O. Box 1693
Bountiful, Utah 84011

Re: K142269
Trade/Device Name: Reliance Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: May 15, 2015
Received: May 14, 2015

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142269

Device Name
Reliance Cervical IBF System

Indications for Use *(Describe)*
The RELIANCE CERVICAL IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The Reliance Cervical IBF and Reliance Cervical IBF-HA implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The RELIANCE CERVICAL IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The RELIANCE CERVICAL IBF System is to be used in patients who have six weeks of non-operative treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Reliance Medical Systems, LLC
545 West 500 South, Suite 100
Bountiful, UT 84010
Telephone: 801-295-3280
Fax: 801-294-0079

26 October 2014

Contact: Bret M. Berry
Member-Manager

510(k) Number:	
Common or Usual Name:	Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name:	Reliance Cervical IBF System
Classification Name:	Class II, Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Product Code:	OVE, ODP

Substantial Equivalence

The Reliance Cervical IBF is substantially equivalent to the legally marketed Reliance Cervical IBF (K120396 and K131429). The primary predicate is the Reliance Cervical IBF (K120396). Arena-C® HA PEEK Cervical Intervertebral Body Fusion Device cleared in K142026 is an additional predicate device. The Reliance Cervical IBF is substantially equivalent to itself in terms of material, strength, intended use, levels of attachment, size range, and use with supplemental fixation. Mechanical testing was performed on the Reliance Cervical IBF System following ASTM F-2077, ASTM F-2267, and ASTM Draft F-04.25.02.02. The mechanical testing included static compression, dynamic compression, static torsion, dynamic torsion, expulsion, and subsidence testing. Additionally, and ovine fusion study was performed.

Device Description

The Reliance Cervical IBF System is comprised of implants and instrument components. The implant component, the Reliance Cervical IBF device, is a spacer, which inserts between vertebral bodies in the anterior column of the cervical spine. The spacer may be made of PEEK Optima LT1 or PEEK Optima LT1-HA with Tantalum markers. The Reliance Cervical IBF System may also include bone screws to secure the device to the vertebral body.

Intended Use/Indications for Use

The Reliance Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The Reliance Cervical IBF and Reliance Cervical IBF-HA implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The Reliance Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical disc disease (defined at neck pain of discogenic origin with

degeneration of the disc confirmed by history and radiographic studies). The Reliance Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

Performance Data and Substantial Equivalence

Mechanical testing was performed on the Reliance Cervical IBF System following ASTM F-2077, ASTM F-2267, and ASTM Draft F-04.25.02.02. The mechanical testing included static compression, dynamic compression, static torsion, dynamic torsion, expulsion, and subsidence testing. Additionally, and ovine fusion study was performed. The Reliance Cervical IBF System was found to be substantially equivalent to itself. Additionally, the Reliance Cervical IBF System is substantially equivalent to itself in terms of sterilization and biocompatibility.